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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,666	11/15/2001	David Botstein	P2730P1C42	4941

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EXAMINER	
DEBERRY, REGINA M	
ART UNIT	**PAPER NUMBER**
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/997,666	**Applicant(s)** BOTSTEIN ET AL.	
	Examiner Regina M. DeBerry	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *124-127 and 129-131*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *122 and 123*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

1/25/07

Continuation of 11. does NOT place the application in condition for allowance because: Claims 122-123 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pages 3-7 of the previous Office Action (15 September 2006).

Applicant discusses the rejection from the previous Office Action. Applicant states that the instant claims are directed to a genus of native sequence polypeptides that are at least 95-99% identical to SEQ ID NO:401, which additionally has the functional recitation that, "the nucleic acid encoding the polypeptide is overexpressed in lung or colon adenocarcinomas". Applicant draws the Examiner's attention to Example 14 of the Synopsis of Application of Written Description Guidelines. Applicant contends that the criteria has been been meet in the instant case.

Applicant's arguments have been fully considered but are not deemed persuasive. The limitation, "wherein the nucleic acid encoding the polypeptide is amplified in lung or colon adenocarcinomas" is a feature of the nucleic acid encoding the polypeptide, NOT an activity limitation for the claimed polypeptides. The claimed genus of polypeptides is not limited by a required function, thus Example 14 from the Written Description Guidelines is not applicable to the instant case. Furthermore, there is no biological activity, expression pattern, phenotype, disease/condition or any other specific feature that is disclosed as being associated with an isolated polypeptide having less than 100% identity to SEQ ID NO:401. The instant specification contemplates but does not exemplify variants of the protein wherein the variant can have any number of substitutions, deletions, insertions and/or additions in SEQ ID NO:401, wherein said nucleic acid encoding said polypeptide is overexpressed in lung or colon tumor cells. Thus, it is unpredictable, based upon percent identity, which variant would share the same function as SEQ ID NO:401.The specification does not disclose any particular portion of polypeptide structures (comprising SEQ ID NO:401) that must be conserved in order to conserve the required function. The disclosure is limited to a single polypeptide. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claims 122-123 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: "an isolated native sequence polypeptide comprising the amino acid sequence of SEQ ID NO:401...", does not reasonably provide enablement for an isolated native sequence polypeptide having at least 90%, 95% or 99% amino acid sequence identity to SEQ ID NO:401...". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 7-9 of the previous Office Action (15 September 2006).

Applicant recites the legal test for enablement and MPEP 2164.08. Applicant argues that overexpression of the claimed polypeptides in lung tumor cells is a functional limitation which indicates the functional purpose (i.e. use in the diagnosis of cancer) of the claimed polypeptides.

Applicant's arguments have been fully considered but are not deemed persuasive. As was stated above, the limitation, "wherein the nucleic acid encoding the polypeptide is amplified in lung or colon adenocarcinomas" is a feature of the nucleic acid encoding the polypeptide, not an activity limitation for the claimed polypeptides. The specification fails to teach how to make variant sequences of SEQ ID NO:401, which could be used in cancer treatment. There is no biological activity that is disclosed as being associated with an isolated polypeptide having less than 100% identity to SEQ ID NO:401. Thus, it is unpredictable, based upon percent identity, which variant would share the same function as SEQ ID NO:401. The specification does not disclose any particular portion of polypeptide structures (comprising SEQ ID NO:401) that must be conserved in order to conserve the required function. The disclosure is limited to a single polypeptide. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.